APPENDIX A: INFORMATION ON PHARMACUETICAL PRICING FROM GOVERNMENT SOURCES

1. This appendix reviews many of the statements from governmental sources regarding the acquisition costs and reimbursement rates for pharmaceuticals. The primary focus is statements made with respect to Medicare Part B drugs, which are primarily physician-administered drugs ("PADs"). In addition, I review some of the comments related to the Medicaid prescription drug program, which primarily covers self-administered drugs ("SADs"), and other government programs that involve prescription drugs. Included in this review are comments expressing how information gleaned from one program informs thinking about another program.

I. 1960S

2. In May 1967, John Gardner, the Secretary of Health, Education, and Welfare ("HEW"),[1] established a Task Force on Prescription Drugs, whose charge was to "[u]ndertake a comprehensive study of the problems of including the cost of prescription drugs under Medicare."[2] In an August 1968 memorandum, Irwin Wolkstein, Assistant Director, Division of Policy and Standards, HEW, criticized reimbursement that was based on a pharmacy's actual acquisition cost, saying that auditing would be expensive as well as "… incapable of accurate finding in a field where prices vary in the course of a year and rebates of various kinds are common."[3] In addition, he wrote, "A proposed alternative acquisition cost basis is the Red book [*sic*] – a listing of prices of manufacturers which is often violated by volume and other discounts to [*sic*] which would be subject to abuse by manufacturers setting prices high to advantage retailers."[4]

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1 HEW is now known as the Department of Health and Human Services ("DHHS").

2 U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs, Background Papers, *The Drug Makers and the Drug Distributors*, December 1968, p. viii.

3 Memorandum from Irwin Wolkstein, Assistant Director, Division of Policy and Standards, HEW, to Joseph A. Higgins, Drug Task Force, *et al*., August 6, 1968, p. 1.

4 *Ibid*.

3. In their final report in 1969, the Task Force considered four alternative bases for reimbursement for product costs, namely: actual acquisition cost, as verified by audit; 'usual and customary charges;' listed wholesale price; and fixed program payment.[5] In their discussion of using listed wholesale price, they point out that "… these listed prices rarely have any realistic relationship with actual acquisition costs."[6] The assumption behind consideration of this method was that "… any losses incurred by the program as a result of basing reimbursement on listed wholesale costs would be made up to the program in savings on auditing and other administrative costs."[7] The Task Force opined that the *Red Book* and *Blue Book* should not be used as the sole determinant of wholesale prices and that price listings should be compiled and revised frequently.[8]

II. 1970s

4. Based on "[s]tudies of drug prices in the multiple-source market [that] indicate that savings of 22 to 36 percent would result from the dispensing of lower cost equivalent products,"[9] HCFA established the Maximum Allowable Cost ("MAC") program in 1974. This program limited reimbursement for multiple-source drugs to the lowest price at which chemically equivalent drugs are generally available.[10]

5. HEW recognized that published wholesale prices (i.e., AWPs) for the single-source drugs not covered under the Federal MAC policy were higher than

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5 "Final Report," Task Force on Prescription Drugs, February 7, 1969, reproduced in Prescription Drugs under Medicare: The Legacy of the Task Force on Prescription Drugs, Part 1, *Journal of Research in Pharmaceutical Economics*, Volume 10 Numbers 2/3 ("Task Force Report 1969"), pp. 146-147.

6 Task Force Report 1969, p. 148. At p. 147, the Report also states, "Under the pricing system now prevalent in the drug industry, the published wholesale price of a drug product is subject to a complex system of frequently changing discounts, including discounts based on the purchase of other drug products, and cumulative discounts based on volume that may be computed after the end of the accounting year."

7 Task Force Report 1969, p. 148.

8 Task Force Report 1969, p. 148.

9 39 Fed. Reg. 40303 (November 15, 1974).

10 39 Fed. Reg. 40303 (November 15, 1974).

what providers actually paid.[11] Under Medicaid, state agencies were free to determine their drug reimbursement policies, and HEW noted that there were a number of methods in use stating, "Some States reimburse providers on the basis of published wholesale prices; others pay on the basis of published prices less a volume discount to the program; still others pay the actual cost to the provider. Similar inconsistencies exist in other Department supported programs."[12]

6. In comments reported in the Federal Register on July 31, 1975, the Secretary of HEW described his position regarding the use of AWPs as a proxy for actual acquisition cost, stating,

> "The Secretary disagrees, however, that average wholesale price should be used as the basis for 'actual acquisition cost' determinations. Average wholesale price is not currently determined by surveying drug marketing transactions (i.e., by determining the actual price a pharmacist pays to a manufacturer or wholesaler for a particular drug product), and thus published wholesale prices often are not closely related to the drug prices actually charged to, and paid by, providers."[13]

7. Reimbursement based on actual acquisition cost had been abandoned due to "widespread opposition [due] to the potential difficulties pharmacists would incur in recordkeeping and invoicing procedures and the administrative problems of tracking deferred and cumulative discounts to pharmacists on their drug purchases."[14]

III. 1980s

8. In 1984, the OIG issued a report on Medicaid prescription drug costs that stated, "Excessive payments are being made nationwide for the ingredient cost of prescription drugs under the Medicaid program."[15] The OIG found that most state

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11 39 Fed. Reg. 40303 (November 15, 1974).

12 39 Fed. Reg. 40303 (November 15, 1974).

13 40 Fed. Reg. 32284 (July 31, 1975) at 32293.

14 HCFA, *EAC Survey Report, California Medi-Cal Program*, EAC Patrol Initiative, 1986 ("EAC Patrol Initiative 1986"), p. 1.

15 OIG, *Changes To The Medicaid Prescription Drug Program Could Save Millions*, A-06-40216, 1984 ("OIG 1984"), p. 3.

Medicaid programs continued to reimburse at AWP.[16] According to the OIG, AWP was not an adequate estimate of prices providers paid, as AWP represented a list price and did not reflect discounts, rebates or free goods that appeared on pharmacists' invoices.[17] HCFA agreed with the OIG's observations that AWP was not the best estimate of actual acquisition cost, but noted that replacing AWP, as was proposed by the OIG, was not economically feasible at that time.[18]

9. During discussion of issues related to Medicare outpatient drug coverage in 1987, the GAO was asked how lessons learned from HCFA's experience with Medicaid prescription drugs could be used in designing a program for Medicare.[19] The GAO recognized that the AWPs listed in the *Red Book* and *Blue Book* overstated the actual acquisition cost of drugs.[20]

10. In August 1989, the Senate Special Committee on Aging published a Majority Staff Report that said, "DVA [Department of Veteran Affairs] achieves an average discount of 41% off the manufacturer's published 'Average Wholesale Price' (AWP) for single source drugs (those still under patent), and an average of 67% off the published AWP for multiple source drugs."[21] The report also stated, "Hospitals, Health Maintenance Organizations, and nursing homes that contract with wholesalers to purchase prescription drugs from a predetermined list are able to achieve discounts of up to 99% off the manufacturer's published 'Average Wholesale Price' (AWP), even for brand name products."[22]

11. In 1989, the OIG indicated that it continued to "believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or

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16 OIG 1984, p. 2.

17 OIG 1984, p. 22.

18 OIG 1984, pp. 24-25.

19 GAO, Testimony of Michael Zimmerman, *Issues Related to Possible Coverage of Outpatient Prescription Drugs Under Medicare*, Subcommittee on Health, Committee on Ways and Means, House of Representatives, GAO/T-HRD-87-15, June 2, 1987, p. 2.

20 *Ibid.*, p. 3.

21 "Prescription Drug Prices: Are We Getting Our Money's Worth?," A Majority Staff Report of the Special Committee on Aging, United States Senate, August 1989, p, 11.

22 *Ibid.*

Medicare programs,"[23] and recommended that for Medicare, "…HCFA consider using a reimbursement method other than AWP or [use a] discounted AWP similar to the Medicaid approach," because AWP was not a "meaningful payment level."[24]

IV. 1990s

12. In June 1991, HCFA proposed basing Medicare Part B drug payments on 85 percent of the national AWP.[25] In its November 1991 final regulations, HCFA based reimbursement on the lower of the national AWP or the carriers' estimate of acquisition costs, noting that oncologists had responded that the 85 percent of AWP standard was inappropriate.[26] According to HCFA, "The thrust of most of the comments was that many drugs could be purchased for considerably less than 85% of AWP—particularly multi-source drugs—while others were not discounted."[27]

13. In 1992, the OIG reported on a study on the cost of dialysis-related drugs that found that "dialysis facilities purchase separately billable drugs significantly below the AWP."[28]

14. Also in 1992, the OIG reviewed physician costs for 13 high-dollar-volume chemotherapy drugs paid for by Medicare, finding that these chemotherapy drugs could be purchased at discounts to AWP and that AWP was "… not a reliable indicator of the cost of a drug to physicians."[29] A study of physician invoices

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23 OIG, *Use of Average Wholesale Prices In Reimbursing Pharmacies Participating In Medicaid and the Medicare Prescription Drug Program*, A-06-89-00037, October 1989 ("OIG Oct 1989"), p. 7.

24 OIG Oct 1989, p. 2.

25 56 Fed. Reg. 25792 (June 5, 1991).

26 CRS, Memo from Thomas Nicola (CRS) to the House Committee on Energy and Commerce regarding Regulatory and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price, August 31, 2001 ("CRS Aug 2001"), pp. 2-3.

27 56 Fed. Reg. 59502 (November 25, 1991), at 59524.

28 Letter from Bryan B. Mitchell, Principal Deputy Inspector General, to William Toby, Acting Administrator, HCFA, attaching OIG, *Cost Of Dialysis-Related Drugs*, A-01-91-00526, October 1992 ("OIG Oct 1992"), p. 1.

29 OIG, *Physicians' Costs For Chemotherapy Drugs*, A-02-91-01049, November 1992 ("OIG Nov 1992"), pp. 1-2 and 5. As part of their study, the OIG staff interviewed *Red Book* officials, who

confirmed that physicians' acquisition costs were significantly less than AWP, and the OIG found that the acquisition cost/AWP relationship varied depending on the manufacturer, regardless of whether the drug was multi-source. For single-source drugs, invoice costs were 20 percent lower than AWP for purchases directly from the manufacturer and 12 to 18 percent lower than AWP for purchases through oncology wholesalers. For multi-source drugs, invoice prices were between 20 and 83 percent lower than AWP for purchases directly from manufacturers and between 9 and 83 percent lower than AWP for purchases through oncology wholesalers.[30]

15. In late 1992 and early 1993, the GAO conducted a study comparing drug purchase costs and Medicaid reimbursements in Illinois and Maryland and found that all nine pharmacies studied purchased drugs at prices below AWP, with an average discount of 26 percent and a range of discounts of 16 to 42 percent below AWP.[31]

16. A 1993 GAO survey looked at the impact of the Medicaid rebates on prices offered to four Health Maintenance Organizations ("HMOs") and eight hospital group purchasing organizations ("GPOs").[32] The HMOs received average discounts off published list prices of 32 percent in 1990 and 34 percent in 1991. The average discounts for inpatient drugs purchased by the GPOs were 27 percent in 1990 and 28 percent in 1991, while the discounts for outpatient drugs purchased by the GPOs were 29 percent in both years. The discounts to AWP in 1990 ranged from 2 to 99 percent.[33]

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said that information from the *Red Book* was "… meant to approximate the cost to the retailers (pharmacists) only." The officials also "… emphasized that their focus has always been the pharmacy sector" and that the manufacturers who supplied pricing information to the *Red Book* were well aware of this. (Appendix II.)

30 OIG Nov 1992, Appendix III.

31 GAO, *Medicaid Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland*, GAO/HRD 93-55FS, March 1993, pp. 5-6.

32 GAO, *Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions*, GAO/HRD-93-43, January 1993 ("GAO Jan 1993"), pp. 1-2.

33 GAO Jan 1993, pp. 18-19.

17. In June 1994, HCFA sent a letter to its regional carriers requesting that they determine EACs for eleven high volume drugs.[34] They noted, "In addition to the EAC, consider allowing an additional fee for the overhead of handling or dispensing drugs. For example, you might determine that an overhead allowance of 10% above the material costs would be equitable in establishing EAC. However, in no case can the cost of the drug plus a dispensing fee exceed the AWP for the drug."[35]

18. In February 1996, the OIG reported that "… Medicare allowed a higher price to drug suppliers [than Medicaid] for two of the three [nebulizer] drugs reviewed because of the manner in which it used the AWP to determine the drug price. This resulted in increased costs to the Medicare program of over $11.7 million."[36] In May 1996, the OIG released a report on pricing of albuterol sulfate that found that 16 percent of retail pharmacies surveyed charged "at least 30 percent less for generic versions of albuterol sulfate than Medicare would have allowed for the same drugs."[37] They also found that pharmaceutical buying groups paid prices that were between 56 and 70 percent less than the Medicare allowance.[38]

19. In September 1996, the OIG issued a report on pharmacy acquisition costs and estimated that AWP exceeded invoice prices by 16.9 percent for branded drugs and 45.2 percent for generic drugs for North Carolina, and by 18.3 percent for branded drugs and 42.5 percent for generic drugs for the nation as a whole.[39]

20. A 1997 study by the OIG revealed that for 22 drugs (mostly PADs), Medicare's reimbursement allowances exceeded actual wholesale prices and that "[t]otal

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34 Letter from M.J. Christenberry, Associate Regional Administrator, Division of Medicare, HCFA Regional Office VI, to All Regional Carriers, "Determination Of Cost Of Drugs—Action," Regional Carrier Letter No. 94-19, June 8, 1994, pp. 1-2.

35 *Ibid*., p. 4.

36 OIG, *Medicare Payments for Nebulizer Drugs*, OEI-03-94-00390, February 1996, p. 6.

37 OIG, *A Comparison Of Albuterol Sulfate Prices*, OEI-03-94-00392, June 1996, p. 4.

38 *Ibid*., p. 5.

39 OIG, *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the North Carolina Department of Human Resources*, A-06-95-00071, September 1996 ("OIG Sep 1996"), p. 1.

allowed charges for the 22 drugs would have been reduced by 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP were the basis for Medicare reimbursement [in 1996]."[40] The average discount in 1995 was 35 percent,[41] and discounts from AWP in 1995 ranged from 15 to 29 percent for single-source drugs and 45 to 95 percent for multi-source drugs.[42] The 1997 study also revealed that,

> "Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. …. For some drug codes, the differences in allowed amounts were significant. Carriers' allowed amounts varied even for single-source drugs where the reimbursement rate is based on only one AWP. A carrier reimbursed code J9217 (leuprolide acetate, a single-source drug) at $496.25 for all of 1995. Another carrier allowed $412.29 for the first quarter of 1995, $439.30 for the second and third quarters, and $477.50 for the fourth. For the first quarter of 1995, providers in one State were receiving 20 percent more in reimbursement than providers billing the same drug code in another State."[43]

21. In 1998, HCFA proposed revising the method of calculating reimbursements for multi-source drugs, noting that the "… AWP for the brand name products was ignored on the presumption that the brand AWP always was higher than the generic AWPs … while this presumption may have been true when the policy first was promulgated in 1991, it was not always true in 1998."[44] Consequently, the final rule established that "[t]he charge allowed by Medicare for drugs and biologicals would be the lower of 95 percent of the median generic AWP or 95 percent of the lowest brand AWP."[45]

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40 OIG, *Excessive Medicare Payments For Prescription Drugs*, OEI-03-97-00290, December 1997 ("OIG Dec 1997"), p. 7.

41 OIG Dec 1997, p. 7.

42 OIG Dec 1997, Table C-2.

43 *Ibid*., p. 9.

44 CRS, Memo from Thomas J. Nicola (CRS) to the House Committee on Energy and Commerce regarding Regulatory and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price, August 31, 2001 ("CRS Aug 2001"), pp. 2-3.

45 CRS Aug 2001, p. 4.

22. The OIG once again compared Medicare allowances with available pricing information for albuterol sulfate in August 1998 and found that (1) "Medicare allowed up to 333 percent more than acquisition costs available [through GPOs] for albuterol sulfate in 1998" and (2) "Customers of mail-order pharmacies will pay up to 30 percent less than Medicare for albuterol sulfate in 1998."[46]

23. "Late in 1998, HCFA reportedly attempted to use the inherent reasonableness authority … to reduce what it considered excessive reimbursement for several items."[47] Congress suspended this authority in 1999.[48]

24. A provision in BBA 1997 required the Secretary of HHS to report to Congress about the impact of the reduction in the Medicare payment rate on AWPs of drugs covered by Medicare.[49] The Secretary's response ended with the statement, "Conclusions are further obfuscated by the OIG finding cited earlier in this report that, as an unregulated, suggested price, typically set by the manufacturer, the AWP bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace."[50]

25. In a report entitled "High Cost Drugs Under the Outpatient Prospective Payment System ["OPPS"]" prepared for HCFA, the researchers state, "Average hospital acquisition cost for single-source innovator drugs was found to be 67% of AWP, with a standard deviation of 12%. Multi-source drugs were heavily discounted from AWP, with an average acquisition cost of 42% of AWP, and a standard deviation of 24%. This higher standard deviation reflects the broad distribution of acquisition costs, which ranged from 10% to 85% of AWP."[51] They also state, "Although a few [single-source] drug products had substantial discounts, the

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46 OIG, *Are Medicare Allowances for Albuterol Sulfate Reasonable?*, OEI-03-97-00292, August 1998, p. 8.

47 CRS Aug 2001, p. 5.

48 CRS Aug 2001, p. 5.

49 Donna E. Shalala, Secretary DHHS, *Report to Congress: The Average Wholesale Price for Drugs Covered under Medicare*, 1999, p. 1. The Report was due on July 1, 1999.

50 *Ibid*., p.8.

51 "High Cost Drugs Under the Outpatient Prospective Payment System," Kathpal Technologies, Prepared under contract by Myers and Stauffer LC, September 8, 1999, p. 4.

overwhelming majority of single source brand name drugs clustered in a uni-modal distribution between 60% and 85% of AWP."[52]

26. In calculating pass-through payments under OPPS, HCFA "… applied the following average ratios of acquisition cost to AWP… .68 for drugs with one manufacturer, .61 for multi-source drugs, and .43 for multi-source drugs with generic competitors."[53]

V. 2000 TO THE PRESENT

27. Thomas J. Bliley, Chairman of the Committee on Commerce, wrote to Donna Shalala, Secretary of HHS, in May 2000, expressing concern over the "… excessive reimbursements that the Medicare program is paying for certain covered pharmaceuticals and other related products."[54] According to the Chairman, the Committee had conducted its own investigations and found that Medicare paid "… considerably more for certain drugs than the actual average price paid by … wholesalers."[55] In addition, he expressed his deep displeasure with HCFA having failed to remedy the problem of having different carriers reimburse at different rates.[56]

28. In May 2000, First DataBank provided revised AWPs for 51 drugs (*ca*. 400 drug codes) to Medicaid programs. These AWPs were based on wholesale price data collected by the DOJ and the National Association of Medicaid Fraud Control Units in the late 1990s.[57] According to the DOJ, purchasers often received further

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52 *Ibid*., p. 25.

53 HCFA, "Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services," 65 Fed. Reg. 18434 (April 7, 2000) at 18481. This provision applies to those drugs for which HCFA did not have valid cost data.

54 Bliley Letter to Shalala May 2000, p. 1.

55 Bliley Letter to Shalala May 2000, p. 1.

56 Bliley Letter to Shalala May 2000, p. 2.

57 Congressional Research Service, O'Sullivan, Jennifer, *Medicare: Payments for Covered Prescription Drugs*, May 21, 2002, p. 6.

discounts below the advertised wholesale catalog prices, therefore actual acquisition prices would be even lower.[58]

29. In a report published in June 2000, the OIG showed that the VA median cost for albuterol was 85.1 percent lower than the Medicare allowance (then 95 percent of AWP), with discounts of 48.9 percent for the Medicaid upper limit price, 46.8 percent for the internet pharmacy median price, and 20 percent for the chain pharmacy median price.[59]

30. On September 5, 2000, Senator John Ashcroft introduced a bill, "Cancer Care Preservation Act." Senator Ashcroft expressed concern about the proposed Medicare cuts in outpatient drug reimbursement through use of revised AWPs and discussed the awareness of the cancer community, the GAO and the HCFA of the inadequacy of reimbursement for professional services.[60] The Senator said that the planned cuts in Medicare reimbursement would force physicians to send patients back to the hospital for treatment, but his bill would place restrictions on HCFA's ability to implement any changes to payment for outpatient cancer treatment, unless agreed to by the GAO, MedPAC, and members of the cancer community, and also would require the GAO to conduct a nationwide analysis to determine the appropriate payment rates for cancer services administered to Medicare beneficiaries.[61]

31. The OIG published a report comparing Medicare and Veterans Affairs prices in September 2000.[62] In that report, they stated, "We estimate that Medicare

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58 DHHS, HCFA, Program Memorandum—Intermediaries/Carriers, *An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program*, Transmittal AB-00-86, September 8, 2000 ("Transmittal AB-00-86"), p. 1.

59 OIG, *Medicare Reimbursement of Albuterol*, OEI-03-00-00311, June 2000, p. 15.

60 Statements on Introduced Bills and Joint Resolutions, By Mr. Ashcroft (for himself, Mr. Hagel, and Mr. Abraham), Statement regarding S. 3003, the Cancer Care Preservation Act, Congressional Record – Senate, September 5, 2000, S8022-8023 ("Ashcroft Statement Sep 2000), p. S8022.

61 Ashcroft Statement Sep 2000, pp. S8022-23.

62 The report, OIG, *Medicare Reimbursement of Prescription Drugs*, OEI-03-00-00310 ("OEI-03-00-00310"), is dated January 2001. A later report, OIG, *Medicare Payments for Prescription Drugs*, Response to Request from Representative W.J. Tauzin, OEI-03-01-00490, June 2001, refers to OEI-03-00-00310 as a September 2000 report.

payments for 24 drugs exceeded actual wholesale prices by $761 million a year. This represents 25 percent of the $3.1 billion Medicare and its beneficiaries reimbursed for these drugs in 1999."[63] The report also looked at the differences in reimbursement rates among carriers, noting that the difference between the low and high reimbursement rates for the J-code J0640 was in excess of 100 percent and the difference exceeded 10 percent for an additional five drugs.[64] The report tabulated reimbursement rates for 10 Medicare carriers for 21 J-codes reimbursed by carriers and 3 J-codes reimbursement by DMERCs.[65]

32. Nancy-Ann Min DeParle, the HCFA administrator, wrote Congress to inform the Congressional Members that HCFA was planning to provide the revised AWPs to the Medicare carriers. She noted that

> "As we have gathered information on many of the drugs reviewed by DOJ, we have concluded that Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate. Therefore, in addition to instructing carriers not to use the DOJ data for the 17 drugs related to chemotherapy and clotting factors, we plan to take administrative action on chemotherapy administration payments and work with Congress to enact legislation regarding clotting factors."[66]

33. On September 8, 2000, HCFA sent a Program Memorandum to its carriers, authorizing them to use revised AWPs for 32 drugs covered by Medicare.[67] HCFA noted that the DOJ data indicate "… an average wholesale price of $22 for one albuterol sulfate NDC which is substantially less than the $73 average wholesale price in the Redbook and compares to $15 from a GPO."[68] HCFA

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63 OEI-03-00-00310, p. 7. Note: the comparison is between reimbursement (at 95 percent of AWP) and the catalog price.

64 OEI-03-00-00310, pp. 8-9.

65 OEI-03-00-00310, p. 15.

66 Letter to Members of Congress from Nancy-Ann Min DeParle, HCFA Administrator, reproduced in *Medicare Part B Resource: Focused Information for Medicare Part B Providers in Maine, Massachusetts, New Hampshire, and Vermont*, October/November 2000, published by the National Heritage Insurance Company of Hingham, Massachusetts, pp. 17-18.

67 Transmittal AB-00-86, p. 1.

68 Transmittal AB-00-86, p. 1.

withdrew its authorization for the use of the revised AWPs on November 17, 2000.[69]

34. Thomas Bliley, Chair House Committee on Energy, wrote Nancy-Ann Min DeParle, HCFA Administrator, on September 25, 2000, in response to her letter of September 8, 2000, discussing the revised AWPs. He noted,

> "Echoing the previous findings of numerous reports by the Department of Health and Human Services' Office of Inspector General (OIG), the [Commerce] Committee has uncovered substantial evidence that Medicare reimburses health care providers at prices dramatically more than what they actually pay for certain drugs. … 1999 prices for Vancomycin, the Abbot Labs-manufactured antibiotic, which a health care provider could buy for $76.00, but for which the AWP upon which Medicare reimbursement was based was $261.84. Similarly, in 1998 a health care provider could buy Gensia's Etoposide for $14.00, while the AWP used to determine Medicare's reimbursement was $141.97."[70]

35. Legislation passed in 2000 imposed a moratorium on "… any direct or indirect decrease in reimbursement for drugs under the current payment methodology …," effective for drugs distributed after January 1, 2001, and directed the GAO to study Medicare reimbursement for drugs and biologicals and also study whether the practice expense component was adequate compensation for administration of these drugs.[71]

36. In September 2001, the GAO issued a report which found that physicians could obtain Medicare-covered drugs at prices that were below current Medicare payments and that wholesalers and GPOs paid prices below AWP. The GAO found that the average discount from AWP for 16 cancer drugs ranged from 13 to

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69 HCFA, Program Memorandum—Intermediaries/Carriers, *Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program*, Transmittal AB-00-115, November 17, 2000.

70 Letter from Thomas J. Bliley, Chairman, House Committee on Commerce, to Nancy-Ann Min DeParle, Administrator, HCFA, September 25, 2000, p.3. The AWP discount for Vancomycin was 71 percent, and the AWP discount for Etoposide was 90 percent.

71 CRS Aug 2001, pp. 6-7.

34 percent and that two drugs had discounts of 65 and 86 percent, respectively.[72] For drugs supplied through pharmacies, the average discounts from AWP for five inhalation therapy drugs were 69 to 85 percent, and discounts were 14 and 77 percent for two immunosuppressive drugs.[73]

37. In September 2001, CMS Administrator Thomas A. Scully testified before House Subcommittee members that the CMS, OIG, and other parties had long recognized the shortcomings of AWP-based reimbursement for Medicare. He noted that physicians and other providers acquired drugs for prices less than AWP as they obtained discounts that were not reflected in publications such as the *Red Book*.[74] At the same hearing, William Scanlon, Director Health Care Issues at the GAO, referred to AWP as a price that "… may be neither an average nor what wholesalers charge."[75]

38. In March 2002, CMS Administrator Thomas A. Scully testified before a Senate Committee regarding Medicare pricing. He noted:

> "If we simply went to a market survey where we hired one of our contractors, we have 23 carriers in Part B to make these payments and four durable medical equipment carriers, so there are 27 Medicare carriers that make these payments, the inconsistencies—and if we just picked one, let us say we picked Palmetto, which is Blue Cross of South Carolina, which happens to be both in Part B and in durable medical equipment.
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> If we picked one and just said to them, go out and come up with a consistent price across the country in the median of what we pay, because there is so much variation between contractors. That alone would save $500 million a year.

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72 GAO, *Medicare Payments for Covered Outpatient Drugs Exceed Providers' Cost*, GAO-01-1118, September 2001 ("GAO Sep 2001"), p. 4.

73 GAO Sep 2001, p. 17.

74 Testimony of Thomas A. Scully (CMS), Medicare Drug Reimbursements, Transcript of Hearings before the House of Representatives Energy and Commerce Subcommittees on Oversight & Investigations and Health, September 21, 2001 ("Scully (CMS) Testimony 2001"), p. 88.

75 Testimony of William J. Scanlon, Director, Health Care Issues, GAO, *Medicare Part B Drugs: Program Payments Should Reflect Market Prices*, GAO-01-1142T, September 2001, p. 2.

> That would not even be requiring lowering prices, that would just tell our contractors to go out and basically come up with a consistent policy. That would be $500 million a year."[76]

39. Leslie G. Aronovitz, Director of Health Care-Program Administration and Integrity Issues at the GAO, testified in June 2002 that "…Medicare's payments are often not related to market prices that physicians and suppliers actually pay for the products," noting that, "… two inhalation drugs accounting for most of Medicare payments to pharmacy suppliers had widely available discounts averaging 78 percent and 85 percent from AWP."[77]

40. In 2003, the GAO published a report comparing provider costs of purchasing blood clotting factors with Medicare's reimbursement to those providers. The GAO found that in 2001 and the first quarter of 2002, hemophilia treatment centers ("HTCs") obtained prices that were 35 to 48 percent below AWP.[78] They noted that HTCs obtain these discounts through the Public Health Service 340B program and these prices were not available to all Medicare providers of blood clotting factors.[79] The GAO found that other homecare companies received discounts of 22 to 40 percent off AWP for clotting factors.[80]

41. The Medicare Modernization Act of 2003 mandated that the OIG study the difference between Medicare reimbursement for End Stage Renal Disease ("ESRD") drugs and the acquisition cost of those drugs by dialysis facilities. A 2004 report from the OIG found that "[i]n 2003, the 4 largest dialysis providers paid between 12 percent and 68 percent less than the current Medicare

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76 Testimony of Thomas A. Scully, Administrator, CMS, on *Reimbursement & Access To Prescription Drugs Under Medicare Part B*, before the Senate Finance Committee, Subcommittee on Health, March 14, 2002, p. 8.

77 GAO, Testimony of Leslie G. Aronovitz, *Medicare: Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs*, before the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies, GAO-02-833T, June 12, 2002, pp. 7-8.

78 GAO, *Medicare—Payment for Blood Clotting Factor Exceeds Providers' Acquisition Cost*, GAO-03-184, January 2003 ("GAO Jan 2003"), p. 10.

79 GAO Jan 2003, p. 13.

80 GAO Jan 2003, p. 10.

reimbursement amount for the 10 drugs we reviewed."[81] The OIG report noted that the manufacturers' Average Sales Prices ("ASPs") as defined under the MMA[82] for these 10 drugs were 17 percent less than Medicare's reimbursement, concluding that "any reimbursement amount set by CMS may still allow some facilities to profit from purchasing drugs, and others to potentially lose money."[83]

42. In December 2004, the GAO published a report that stated, "Medicare payment rates for the 16 drugs we studied will exceed oncologists' estimated costs for acquiring these drugs by 22 percent in 2004 and 6 percent in 2005."[84] The report also states, "Regarding chemotherapy administration services, we estimate that fees for almost every service will increase in both 2004 and 2005 relative to 2003, in some cases in excess of 300 percent."[85]

43. In a June 2005 report that compared ASP and AWP, the OIG stated, "For 2,077 national drug codes with ASP and AWP data, ASP is 49 percent lower than AWP at the median."[86] For single-source drugs, ASP was 26 percent below AWP, for multi-source brand drugs, ASP was 30 percent lower than AWP, and for generic drugs, ASP was 68 percent less than AWP.[87] In a companion report, also published in June 2005, the OIG compared "AMP [used in the calculation of Medicaid rebates] to AWP and WAC for national drug codes (NDC) reimbursed by Medicaid."[88] This study found that AMP is equal to AWP less 59 percent and AMP is equal to WAC minus 25 percent.[89] For single-source drugs, AMP was 23

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81 OIG, *Medicare Reimbursement for Existing End-Stage Renal Disease Drugs*, OEI-03-04-00120, May 2004 ("OIG May 2004"), p. 8.

82 CMS, "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," Interim final rule with comment period," 70 Fed. Reg. 39022 (July 6, 2005).

83 OIG May 2004, pp. 10 and 13.

84 GAO, *Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs*, GAO-05-142R, December 1, 2004, p. 2.

85 *Ibid*., p. 3.

86 OIG, *Medicaid Drug Price Comparison: Average Sales Price To Average Wholesale Price*, OEI-03-05-00200, June 2005, p. 8.

87 *Ibid*.

88 OIG, *Medicaid Drug Price Comparisons: Average Manufacturer Price To Published Prices*, OEI-05-05-00240, June 2005, pp. i-ii.

89 *Ibid*., p. 9.

percent lower than AWP, for multi-source brand drugs, AMP was 28 percent below AWP, and for generics, AMP was 70 percent lower than AWP.[90]

[90] *Ibid*., p. 11.